

Internal Revenue Service  
Director Director

Department of the Treasury  
P.O. Box 2508 Cincinnati, OH 45201

Person to Contact:

Telephone Number:

Refer Reply to:

EP/EO

Employer Identification Number:

Date: FEB 27 1992

Dear Sir or Madam:

We have considered your application for recognition of exemption from Federal income tax under the provisions of section 501(c)(3) of the Internal Revenue Code of 1986 and its applicable Income Tax Regulations. Based on the available information, we have determined that you do not qualify for the reasons set forth on Enclosure 1.

Consideration was given to whether you qualify for exemption under other subsections of section 501(c) of the Code and we have concluded that you do not.

As your organization has not established exemption from Federal income tax, it will be necessary for you to file an annual income tax return on Form 1041 if you are a trust or Form 1120 if you are a corporation or an unincorporated association. Contributions to you are not deductible under section 170 of the Code.

If you are in agreement with our proposed denial, please sign and return one copy of the enclosed Form 6018, Consent to Proposed Adverse Action.

You have the right to protest this proposed determination if you believe that it is incorrect. To protest, you should submit a written appeal giving the facts, law and other information to support your position as explained in the enclosed Publication 892, "Exempt Organizations Appeal Procedures for Unagreed Issues". The appeal must be submitted within 30 days from the date of this letter and must be signed by one of your principal officers. You may request a hearing with a member of the office of the Regional Director of Appeals when you file your appeal. If a hearing is requested, you will be contacted to arrange a date for it. The hearing may be held at the Regional Office, or, if you request, at any mutually convenient District Office. If you are to be represented by someone who is not one of your principal officers, he or she must file a proper power of attorney and otherwise qualify under our Conference and Practice Requirements as set forth in Section 601.502 of the Statement of Procedural Rules. See Treasury Department Circular No. 230.

2/21/92

2-18-92

2/25/92

[REDACTED]  
[REDACTED]

If you do not protest this proposed determination in a timely manner, it will be considered by the Internal Revenue Service as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Internal Revenue Code provides in part that:

A declaratory judgment or decree under this section shall not be issued in any proceeding unless the Tax Court, the Claims Court, or the district court of the United States for the District of Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service.

If we do not hear from you within the time specified, this will become our final determination. In that event, appropriate State officials will be notified of this action in accordance with the provisions of section 6104(c) of the Code.

Sincerely yours,

[REDACTED]

District Director

Enclosures: 3

cc: [REDACTED]

Enclosure I

[REDACTED]  
[REDACTED]

You were incorporated on [REDACTED] to improve the service of laboratory medicine to patients, physicians, hospitals, and the general public. You issued [REDACTED] shares of stock with one-half going to [REDACTED], President/Treasurer, and one-half going to [REDACTED], Vice-President/Secretary. There are no present plans to pay dividends. On [REDACTED], you amended the purpose clause of your Articles of Incorporation to state that you will improve public safety within the meaning of section 501(c)(3) of the Internal Revenue Code through proficiency testing of laboratory equipment used by physicians and hospitals.

You have indicated your corporation will perform various medical laboratory tests on patient specimens for the purpose of diagnosis and treatment of diseases or conditions. Proficiency testing is part of the quality control required for the instruments. You assist hospitals, laboratories, clinics, blood banks, nursing homes and physicians comply with the two federal laws, Clinical Laboratory Improvement Act of 1967 and 1988. You indicated that there are eight approved proficiency testing providers (including [REDACTED]) which have been approved by U. S. Department of Health and Human Services.

Your income is derived from fees charged for the testing ~~services~~. Your expenses include vendor costs, advertising and marketing expenses, salaries and payroll taxes, travel expenses and professional fees. Vendor costs include the amount of money manufacturers charge to procure raw materials, manufacture specimens, label, perform quality control, package and ship the specimens to you.

Section 501(c)(3) of the Code provides, in part, for the exemption from Federal income tax of organizations organized and operated exclusively for charitable, religious, educational or testing for public safety purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(d)(1)(ii) of the Income Tax Regulations states that an organization is not operated exclusively for one or more exempt purpose unless it serves a public rather than a private interest. It must not be operated for the benefit of designated individuals or the persons who created it.

Section 1.501(c)(3)-1(d)(4) of the Regulations defines the term "testing for public safety" as used in section 501(c)(3) to include the testing of consumer products, such as electrical products, to determine whether they are safe for use by the general public.

Section 1.501(c)(3)-1(d)(5)(i) of the Regulations in defining the term "scientific" provides that since an organization may meet the requirements of section 501(c)(3) only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest.

Section 1.501(c)(3)-1(d)(5)(ii) of the Regulations further provides that scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products.

Revenue Ruling 78-426, 1978-2 C.B. 175 describes a nonprofit organization whose activities include the inspection, testing and safety certification of cargo shipping containers and research, development, and reporting of information in the field of containerization. It is not operating exclusively for the purpose of testing for public safety or scientific purposes. The containers are tested against voluntary standards issued by a federal agency. The testing and certification serve the private interest of the container manufacturers and shippers by facilitating their international operations; they only serve the public interest incidently. The testing and research activities are of a type ordinarily carried on as a commercial industrial operation. The organization fails to qualify for exemption under section 501(c)(3) as it is not operated exclusively for the purpose of testing for public safety or for scientific purposes.

Revenue Ruling 68-373, 1968-2 C.B. 206 describes an organization which engages in clinical testing of drugs for commercial pharmaceutical companies. The tests were required in order to comply with the Food and Drug Administration (FDA) requirements that the drugs be tested for safety and efficacy before they could be made available to the public. The clinical testing of drugs is an activity which is ordinarily carried on by a pharmaceutical company and is a commercial operation. Such testing does not constitute scientific research within the meaning of section 1.501(c)(3)-1(a)(5)(i) of the Regulations. Until a drug is approved for marketing by the FDA, it is not a consumer product, available for general use by the public. Clinical testing of a drug for safety in order to enable the manufacturer to comply with FDA requirements is a service to the manufacturer and as such serves the private interests of the manufacturer. This organization's application for exemption was denied on the basis its activities were not scientific within the meaning of section 501(c)(3) of the Code. In addition, the organization does not engage in testing of consumer products.

You are similar to the organizations described in the above revenue rulings in that your activities do not serve the public interest as required by section 1.501(c)(3)-1(d)(5)(i) of the Regulations. Your proficiency testing activities serve the private interests of hospitals, laboratories, clinics, blood banks, nursing homes and physicians. The proficiency testing of medical equipment for accuracy in order to enable the hospitals, laboratories, clinics, blood banks, nursing homes and physicians to meet the applicable federal requirements is not 'testing for public safety' but is merely a service performed for the owners and users of the instruments. In addition, the medical instruments which are being tested are not consumer products for purposes of section 509(a)(4) of the Code. Accordingly, we have concluded that you do not qualify for exemption from Federal income tax under section 501(c)(3) of the Code and contributions to you are not deductible by donors under section 170 of the Code.